

## Cellabs Product Profile

# PAN MALARIA ANTIBODY CELISA

### INTENDED USE AND PRINCIPLE OF THE TEST

The Pan Malaria Antibody CELISA is for the detection of specific IgG antibody against *P. falciparum*, *P. vivax*, *P. malariae* and *P. ovale* in blood, serum or plasma samples. The indirect ELISA principle is employed using microwells coated with a panel of recombinant *malaria* antigen. The test sample is added and incubated to allow the binding of the antibody-antigen complex, washed to remove any unbound then followed by adding a conjugate of enzyme labelled anti-human monoclonal antibody. The addition of a substrate solution allows the development of a colour proportional to the amount of malarial antibodies present in the serum under test.

For the purpose of defining an infection status. Not for use as a screening assay for the detection of malaria antibodies in blood or organ donations in Australia.

### CONTENTS OF THE KIT

MBCMW	Celisa Plate - 2 x 96 wells - (single use only)	2 plates
CONTROL +	Positive Control	0.10mL
CONTROL -	Negative Control	0.10mL
MBCPO	Enzyme Conjugate (200x)	0.15mL
MBCPT	PBS/Tween (20x)	125mL
MBCSC	Substrate Chromogen (20x)	1.2mL
MBCSB	Substrate Buffer	24mL
MBCSS	Stopping Solution	12mL

All components should be stored at 2-8°C, and are supplied ready for use. Expiry dates are clearly marked on each kit component and on the box and do not change once opened.

### MATERIALS REQUIRED BUT NOT PROVIDED

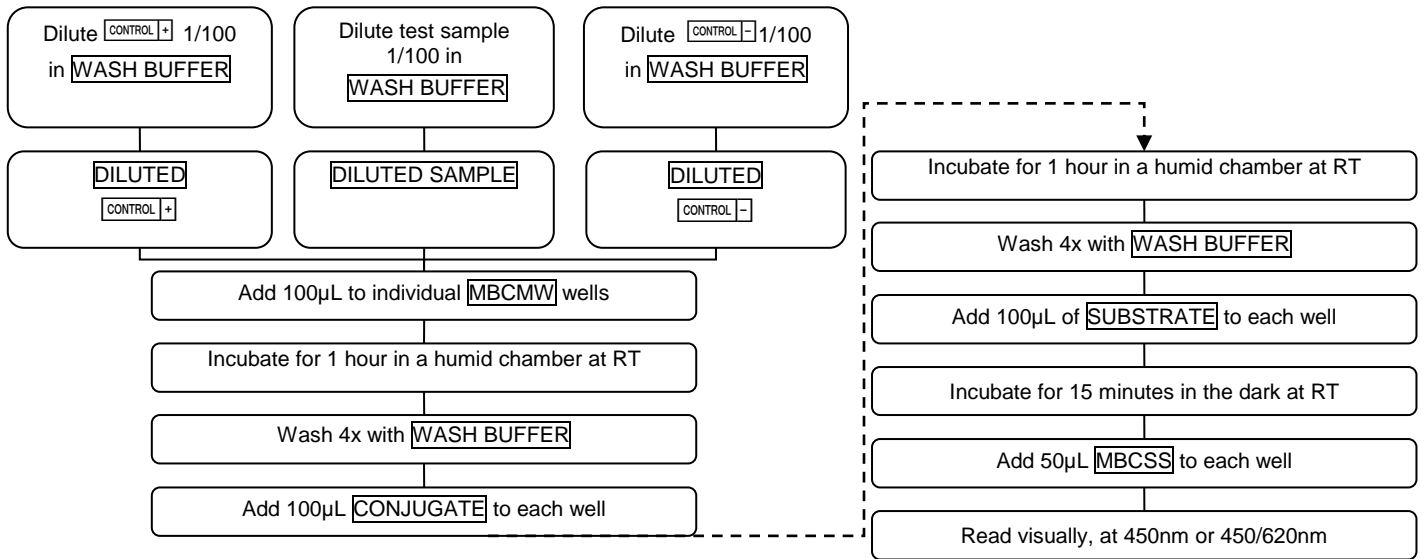
- Micropipettes and tips
- Clean glassware or plastic containers for solutions
- Distilled water
- Humid chamber
- ELISA washer
- Spectrophotometer to read absorbances at a single wavelength of 450nm, or at dual wavelengths of 450nm and 620nm

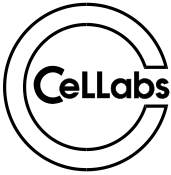
### DIAGRAM FOR USE

Use Cellabs Instructions for Use Insert contained in kit when performing test, and refer to Material Safety Data Sheet (MSDS) for further information.



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## READING AND INTERPRETATION OF RESULTS AND DIAGNOSIS

Samples may be read visually or photometrically. Visually, samples giving the same or less colour than the negative control are considered negative. Samples giving colour greater than the negative control, similar to the positive control, are considered positive. Using a spectrophotometer, negative samples should give an optical density below a certain level and positive samples should give an optical density above a certain level. Please refer to the kit insert for detailed information.

## PERFORMANCE DATA FOR PAN MALARIA ANTIBODY CELISA

### Sensitivity/Specificity

A	n = 173 Samples. Pan Malaria CELISA (Reference test = IFAT )	Sensitivity: 94% Specificity: 100%
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### Repeatability

2 Positive samples were tested in replicates of 8, by 3 different operators. The coefficient of variation for repeatability ranged between 1.71% and 4.41%, with an average of 2.75%.

### Reproducibility

2 Positive samples were tested in replicates of 8, by 3 different operators. The coefficient of variation for reproducibility ranged between 5.72% and 5.90%, with an average of 5.81%.

### Cross reactivity

The Pan Malaria Antibody CELISA does not cross-react with:

- Toxocara sp.
- T. cruzi*
- Leishmania sp.
- W. bancrofti*
- Dengue virus

## For Ordering Assistance:

See Your Local Distributor:

OR

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